

REMARKS

Claims 1-3 and 6-75 are all the claims pending in the application.¹ Claims 4, 5 and 76 were previously canceled.

Reconsideration and review of the claims on the merits are respectfully requested.

Formal Matters

Applicant notes that on the Office Action Summary, the Examiner has apparently indicated in block 2b that this action is non-final. However, the Examiner may have intended to issue a Final Office Action as stated in the Detailed Action, at paragraph 10, page 10. Applicant requests clarification of this point by the Examiner.

Applicant appreciates that the Examiner acknowledges Applicant's claim for foreign priority and receipt of the certified copy of the priority document.

Applicant also appreciates that the Examiner accepts the drawings filed on August 1, 2001.

Objected to, but Allowable, Claims

Applicant appreciates the Examiner's indication that Claims 42 and 44 are objected to for depending on a rejected claim and that Claim 43 is rejected under 35 U.S.C. §112, second paragraph, but the Examiner states that it is free of the prior art.

Applicant submits that these claims, along with the other pending claims, are allowable based on the amendment and comments presented herein, and allowance of these claims is respectfully requested.

Claim Rejections - 35 U.S.C. § 112

Claims 2, 5, 7, 9, 11, 13, 17, 19, 22, 25, 28, 31, 34, 37, 40, 43, 46, 49, 52, 55, 58, 61, 64 and 66-75 are rejected under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The Examiner is still unclear after our response as to what criteria the phrase “and the like” is measured as the terms “and the like” follow such varied terms as sequence, length and composition, and the Examiner recommends that the phrase be deleted.

Applicant responds as follows.

In order to clarify Applicant’s invention and in order to advance prosecution of this application, Applicant deletes the phrase “and the like” as the Examiner suggests from the rejected independent Claims 2, 17, 66, 68 and 70-75.

Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph.

¹ Applicant points out that Office Action Summary indicates that Claims 1, 2 and 5-75 are pending, apparently in error. Applicant requests clarification of which claims are pending in the next Office communication.

Claim Rejections - 35 U.S.C. § 102

A. Claims 1, 2, 6-11, 14-20, 57-65, 70-75 are rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by Potter et al (US 5,837,194) for the reasons given in the Office Action.

B. Claims 1, 2, 5-13, 18, 19, 21, 22, 24, 25, 27, 28, 30, 31, 36, 37, 45, 46, 48, 49, 51, 52, 54 and 55 are rejected under 35 U.S.C. § 102(e) as assertedly being anticipated by Pham et al (US 6,426,050) for the reasons given in the Office Action.

C. Claims 1, 2, 3, 8, 9, 18, 19, 21, 22, 70-72, 74 and 75 are rejected under 35 U.S.C. § 102(e) as assertedly being anticipated by Vuong (US 6,448,089) for the reasons given in the Office Action.

Applicant respectfully traverses the rejections.

In Potter et al, the nylon filters are placed between perforated plates, but since the nylon filters are wrapped in plastic film (column 3, lines 30 to 45) and the nylon filter is not formed with any absorptive region formed by charging an absorptive material in a plurality of holes formed in a substrate, it is clear that there are essential differences between the claimed invention and that of Potter et al.

Pham et al discloses a multi-well platform including a frame made of polymers, glass, quartz or the like and wells disposed in the frame (column 1, lines 56 to 65), and the wells of the multi-well platform comprise an optically opaque material that can interfere with the transmission of radiation, such as light, through the wall of a well or a bottom of a well.

However, since Pham et al. states that optically opaque material can be coated on any surface of the multi-well platform, or be an integral part of the frame or bottom as they are manufactured, it is reasonable to understand that no absorptive material is charged in the wells (column 3, lines 47-53). Therefore, there are also essential differences between the claimed invention and Pham et al.

Similarly, although Vuong refers to a well plate, it does not state that an absorptive material is charged in the wells.

As described above, since none of the cited references disclose or suggest a biochemical analysis unit including a plurality of absorptive regions formed by charging an absorptive material in a plurality of holes formed in a substrate made of a material capable of attenuating radiation energy and/or light energy, the claimed invention is not anticipated by any one of them.

Important advantages result from a biochemical analysis unit according to the present invention in comparison with a biochemical analysis unit which is disclosed in Potter et al, Pham et al or Vuong. In the references cited by the Examiner, the wells of the biochemical analysis unit are not charged with any absorptive material. On the other hand, in the present invention, where a plurality of absorptive regions are formed by charging an absorptive material in a plurality of holes formed in a substrate made of a material capable of attenuating radiation energy and/or light energy, the biochemical analysis unit, for example, prevents a spotted solution from spreading and prevents light emitted from a particular spot from reaching neighboring spots, thereby reducing noise.

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Potter, Pham, Warner and Vuong neither disclose nor suggest the feature of the claimed invention defined in the independent claims that absorptive regions are formed by charging an absorptive material in a plurality of holes formed in a substrate made of a material capable of attenuating radiation energy and/or light energy.

For the foregoing reasons, Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. §102(b)/(e).

Claim Rejections - 35 U.S.C. § 103

A. Claims 33, 34, 39 and 40 are rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over Pham et al for the reasons given in the Office Action.

B. Claims 45-53, 55 and 56 are rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over Potter et al in view of Warner et al (US 4,728,792) for the reasons given in the Office Action.

C. Claims 66-69 are rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over Potter et al, in view of Ogura (US 6,130,440) for the reasons given in the Office Action.

The Examiner recognizes that Potter does not teach stimuable phosphor sheet, but the Examiner's position is that it would have been prima facie obvious to apply Ogura's stimuable phosphor imaging sheet in Potter's device in order to detect bound probes by eliminating the chemical processing.

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D. Claims 23, 26, 29, 32, 35, 38, 41 and 44 are rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over Potter et al in view of Pham et al for the reasons given in the Office Action.

Applicant respectfully traverses the rejections.

Based on the distinctions that Applicant has given above, each of the cited references to Potter, Pham, Warner or Ogura, separately, or in combination with each other, neither discloses nor suggests the feature of the claimed invention defined in the independent claims that absorptive regions are formed by charging an absorptive material in a plurality of holes formed in a substrate made of a material capable of attenuating radiation energy and/or light energy.

In addition to the arguments for traversal of the references as applied in the anticipation rejections above, Applicant submits Declaration evidence of patentability in a Rule 132 Declaration filed concurrently herewith comparing the biochemical analysis unit of the present invention and the closest examples in Potter, Pham and Vuong, which shows that the claimed biochemical analysis unit with the embodiments as recited in, for example, Claims 1 and 2 show unexpectedly superior results in that the noise signals are remarkably reduced.

For the foregoing reasons, Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a).

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the

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Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.


Respectfully submitted,

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23373

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Date: May 17, 2004



PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q65512

Nobuhiko OGURA

Appln. No.: 09/918,500

Group Art Unit: 1637

Confirmation No.: 3311

Examiner: Jeffrey Siew

Filed: August 1, 2001

For: **BIOCHEMICAL ANALYSIS UNIT AND BIOCHEMICAL ANALYZING METHOD
USING THE SAME**

DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Nobuhiko Ogura, hereby declare and state:

THAT I am a citizen of Japan;

THAT I have received a undergraduate in Control Engineering from the Tokyo Institute
of Technology in 1982.

THAT I have received a master's degree in Mechanical Engineering from the Tokyo
Institute of Technology in 1984;

THAT I have been employed by Fuji Photo Film Co., Ltd., since 1996, where I hold a
position as Research Associate, with responsibility for developing a biochemical analysis
system;

THAT I am the sole inventor of the invention described and claimed in the above-
identified application;

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THAT I am familiar with the prosecution of the above-identified application; and

THAT the experimentation set forth below was conducted by me or under my direct supervision.

I hereby submit data substantiating unexpectedly superior results in the present invention, in that noise of the signals were markedly reduced, and thus can be distinguished from conventional results.

A web-like substrate made of SUS304 and having a width of 80 mm and a thickness of 100 μm was first prepared and holes were formed using an etching process in the web-like substrate so that the pitch of neighboring holes was 0.4 mm.

Then, a sheet-like nylon filter "immobilon-Ny" (Product Name) manufactured by Millipore Corporation and having a thickness of 120 μm , and the web-like substrate were superposed and fed to a portion between a pair of rollers heated to 150°C and being in contact with each other under pressure of 40 Mpa, thereby forming a laminate.

The thus formed laminate was cut to a size of 80 x 70 mm to fabricate a biochemical analysis unit sample having a number of absorptive regions.

Then, a DNA molecular weight marker IV (stock solution concentration: 25 ng/ μL) was alternately spotted into the absorptive regions of the thus fabricated biochemical analysis unit sample using a "PixSys5500" spotter (Product Name) manufactured by Cartesian Dispensing Systems and a Quill pin.

Further, an "ULTRAVIOLET CROSSLINKERS" (Product Name) manufactured by ULTRA • LUM, INC as probe DNAs were fixed in the absorptive regions by projecting an ultraviolet ray having energy of 0.07 J/cm^2 onto the biochemical analysis unit sample.

The biochemical analysis unit sample was then dipped in 120 ml of a church hybridization buffer at 68°C for ten minutes.

Further, DIG labeled target DNAs were denatured in a boiled water for five minutes, quickly cooled in an ethyl alcohol solution for one minute and mixed with 120 ml of a church hybridization buffer at 68°C . Then, the biochemical analysis unit sample was dipped in the mixed solution and held for sixteen hours, thereby effecting hybridization.

The target DNAs adhered to the biochemical analysis unit sample without being hybridized with the probe DNAs and were removed by cleaning the biochemical analysis unit sample with 100 ml of a church wash buffer containing 90 ml of a deionized water, 4 ml of church phosphate buffer and 1 gram of SDS for twenty minutes.

Further, the biochemical analysis unit sample was cleaned with a cleaning solution containing 995 ml of a deionized water, 5 ml of $20 \times \text{SSC}$ and 1 gram of SDS for fifteen minutes. This cleaning operation was repeated three times.

Then, ten times concentrated solution of a washing buffer for DIG was diluted with a deionized water ten times, thereby preparing a cleaning solution, and the biochemical analysis unit sample was cleaned with the cleaning solution filled in a vessel at 37°C . Further, the cleaning solution was discharged from the vessel and 6.5 ml of a blocking buffer prepared by

diluting a ten times concentrated solution of a maleic acid buffer for DIG with a deionized water ten times was poured into the vessel.

After the biochemical analysis unit sample was held in the blocking buffer for five minutes, the blocking buffer was discharged from the vessel and a solution prepared by diluting a DIG labeling buffer 20,000 times with a solution for an antigen-antibody reaction was poured into the vessel.

After the biochemical analysis unit sample was held in the diluted DIG labeling buffer for fifteen times, the diluted DIG labeling buffer was discharged from the vessel.

Then, a solution prepared by diluting ten times concentrated solution of a DIG washing buffer with a deionized water ten times was poured into the vessel and the biochemical analysis unit sample was held therein for fifteen minutes.

This washing operation was repeated three times.

Further, a solution prepared by diluting ten times concentrated solution of a Detection buffer with a deionized water ten times was poured into the vessel and the biochemical analysis unit sample was held therein for five minutes.

After the diluted Detection buffer was discharged from the vessel, a CD-Star was poured into the vessel and the biochemical analysis unit sample was held therein for five minutes.

Finally, the biochemical analysis unit sample was taken out from the vessel and held for sixty minutes.

Then, signals recorded in the biochemical analysis unit were read using a CCD camera "LAS-3000" (Product Name) supplied from Fuji Photo Film Co. Ltd.

The results of detection are shown in Figure 1, shown below.

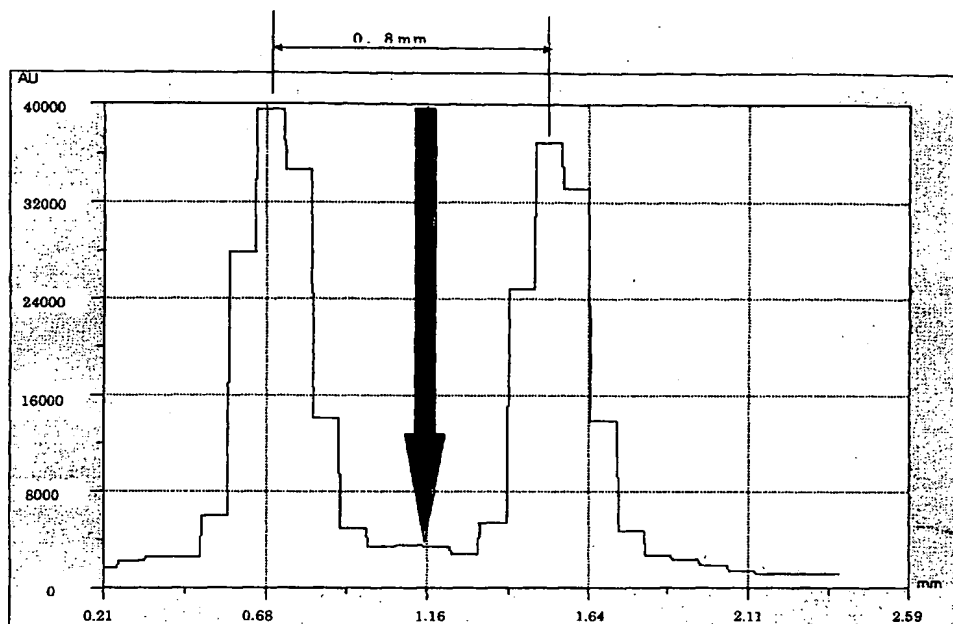


Fig. 1

As shown in Figure 1, it was found that in the case where signals were detected from the biochemical analysis unit sample at a pitch of 0.4 mm, noise detected between the neighboring absorptive regions (spots) was about 10 % of the signal.

Further, instead of the above mentioned biochemical analysis unit sample, a nylon filter "immobilon-Ny" (Product Name) manufactured by Millipore Corporation was used as a biochemical analysis unit comparative sample and a DNA molecular weight marker IV (stock solution concentration: 25 ng/ μ L) was spotted onto the biochemical analysis unit comparative sample at a pitch of 0.9 mm.

Then, the biochemical analysis unit comparative sample was processed in the same manner of processing the biochemical analysis unit sample and signals recorded in the biochemical analysis unit comparative sample were read using a CCD camera "LAS-3000" (Product Name) supplied from Fuji Photo Film Co. Ltd.

The results of detection are shown in Figure 2, shown below:

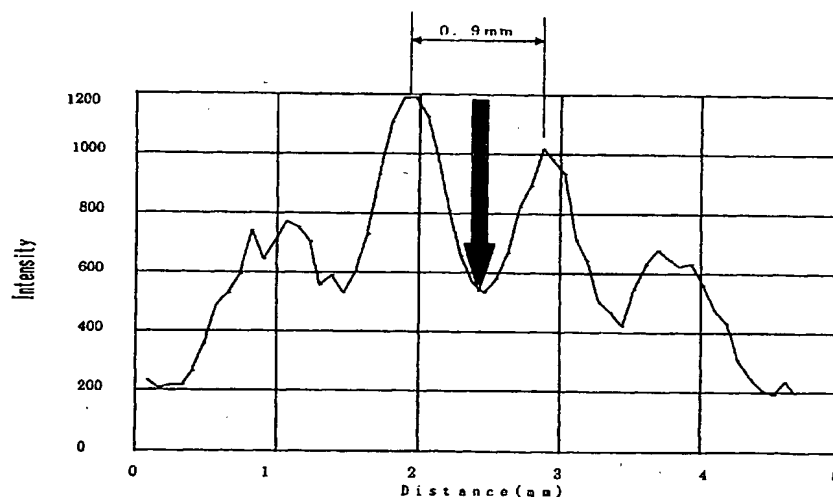


Fig. 2

As shown in Figure 2, it was found that in the case where signals were detected from the biochemical analysis unit comparative sample at a pitch of 0.45 mm, noise detected between the neighboring absorptive regions (spots) was about 45 % of the signal.

Therefore, it was found from Figures 1 and 2 that according to the present invention, noise of the signals could be markedly reduced.

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I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: May 13, 2004


Nobuhiko OGURA